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09/728,911	12/01/2000	Scott R Presnell	99-93	2372

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EXAMINER

ROARK, JESSICA H

ART UNIT PAPER NUMBER

1644

DATE MAILED: 01/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/728,911

Applicant(s)

PRESNELL ET AL.

Examiner

Jessica H. Roark

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 29 September 2003 and 27 October 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,8-18,21-42,47-66 and 68-86 is/are pending in the application.
- 4a) Of the above claim(s) 8-18,21-42,54-66 and 71 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1, 47, 51-53, 68, 70, 72-80 and 83-86 is/are allowed.
- 6) ☒ Claim(s) 48-50,69,81 and 82 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. §§ 119 and 120**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

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### RESPONSE TO APPLICANT'S AMENDMENT

1. Applicant's amendment, filed 10/27/03, is acknowledged.

Claims cancelled: 2-7, 19-20, 43-46, 67.

Claims added: 72-86.

Claims currently amended: 1, 47-49, 51-53 and 68-70.

Claims pending: 1, 8-18, 21-42, 47-66 and 68-86.

Claims 8-18, 21-42, 54-66 and 71 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

*Claims 1, 47-53 and 68-86 are under consideration in the instant application.*

2. This Office Action will be in response to applicant's arguments, received 9/29/03 .

The rejections of record can be found in the previous Office Action.

It is noted that New Grounds of Rejection are set forth herein.

3. Applicant's cancellation of claims 2-3 and 67 has obviated the previous objections and rejections with respect to these claims.

#### ***Priority***

4. Applicant's claim for domestic priority under 35 U.S.C. 119(e) is acknowledged.

Applicant's arguments filed 9/29/03 regarding support for a "multimeric" receptor in provisional application 60/149,049 (filed 12/3/1999) are found convincing.

However, claims 48-49 and 52-53 recite additional limitations regarding the composition of the multimeric receptor that do not appear to have support in provisional application 60/169,049 (filed 12/3/1999). In particular, the Examiner was unable to identify support for multimeric receptors further comprising a soluble Class I or Class II cytokine receptor (claims 48 and 52) or for multimeric receptor complex comprising a soluble CRF2-4 receptor polypeptide (SEQ ID NO:35), a soluble IL-10 receptor polypeptide (SEQ ID NO:36), or a soluble zycotor11 receptor polypeptide (SEQ ID NO:34) (claims 49 and 53).

Claims 48-49 and 52-53 do appear to have adequate written support in provisional application 60/232,219 (filed 9/13/2000).

Applicant is invited to point to adequate written support for these claims in the provisional applications.

#### ***35 USC § 112 second paragraph***

5. Applicant's amendment, filed 10/27/03, has obviated the previous rejection of claims 1-3 and 19-20 under 35 U.S.C. 112, second paragraph.

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***Claim Rejections - 35 USC § 112 first paragraph***

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

*The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.*

7. Claims 50, 69 and 81-82 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. The specification as originally filed does not provide support for the invention as now claimed. *This is a New Matter rejection for the following reasons:*

Applicant's arguments, filed 9/29/03 points to a number of locations in the specification as filed for support for a zcytor16 polypeptide that is labeled with biotin/avidin label, a radionuclide, an enzyme, a substrate, a cofactor, an inhibitor, a fluorescent marker, a chemiluminescent marker, or a cytotoxic molecule.

The rejection of record may be found in full in the previous Office Action and is incorporated herein.

Applicant's argument with respect to labeling with biotin in view of the support on page 41 at lines 11-12 is acknowledged. However the claims recite "biotin/avidin", rather than biotin and this limitation is therefore not fully supported. Applicant should amend the claims to recite that which is disclosed, i.e., "biotin".

Applicant in the Remarks filed 9/29/03 also points to other potential sources of support for the above noted limitations, in particular pages 17, 41, 62, 65, 67, 82, 90-91, 94-96 and Examples 1, 3, 7, 8 and 11. However, these locations do not appear to provide support for labeling the zcytor16 polypeptide recited in the instant claims with the particular labels noted supra.

As previously acknowledged, the specification does lists these various labels in the locations pointed to by Applicant. However, the issue is not simply whether the Application discloses these various additional components which could be linked to the zcytor16 polypeptide, but whether the specification discloses that the cytokine receptor polypeptide may further comprise these component.

It is again acknowledged that these limitations do appear in the specification where noted by Applicant, but they are described only in the context of an antibody or a polypeptide that binds the instantly recited polypeptide. Thus the Examiner maintains that while the words may be found in the specification as filed, the context is lacking.

The instant claims now recite limitations which were not clearly disclosed in the specification and claims as filed, and now change the scope of the instant disclosure as filed. Such limitations recited in the present claims, which did not appear in the specification or original claims, as filed, introduce new concepts and violate the description requirement of the first paragraph of 35 U.S.C. 112.

It is suggested that Applicant limit these claims to the subject matter claimed in original claim 50.

*Applicant is required to cancel the New Matter in the response to this Office Action.*

Alternatively, Applicant is invited to clearly point out the written support for the instant limitations.

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8. Applicant's amendment, filed 10/27/03, has obviated the previous rejection of claims 1-2, 47-53 and 67-69 under 35 U.S.C. 112, first paragraph *written description*.

9. Applicant's amendment, filed 10/27/03, has obviated the previous rejection of claims 1-2, 47-53 and 67-70 rejected under 35 U.S.C. 112, first paragraph, enablement.

***Claim Rejections – 35 U.S.C. § 102***

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

*(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.*

11. Applicant's amendment, filed 10/27/03, has obviated the previous rejection of claims 47 and 50 under 35 U.S.C. 102(e) as being anticipated by Agarwal et al. (WO 01/98342, see pages 1-33, 71-75, 81 and SEQ ID NOS:18-20 and 40-42, of record).

12. The following rejection under 35 U.S.C. § 102 is made under the assumption that the effective filing date for claims 48-49 and 52-53 is 9/13/2000, which is the filing date of provisional application 60/232,219.

13. Claims 48 and 49 are rejected under 35 U.S.C. 102(e) as being anticipated by Agarwal et al. (WO 01/98342, see pages 1-33, 71-75, 81 and SEQ ID NOS:18-20 and 40-42, of record).

Applicant's arguments filed 9/29/03 have been fully considered but have not been found convincing for the reasons set forth supra in the discussion of the priority date of claims 48 and 49.

The teachings of Agarwal et al. are of record. Briefly, Agarwal et al. teach the isolated sbg456548CytoRa polypeptide set forth in SEQ ID NO:41 and that it is a cytokine receptor (see especially SEQ ID NO:41, Table I on page 24, Table II on page 27, Table III on page 31 and Table IV on pages 71-75). The sbg456548CytoRa polypeptide set forth in SEQ ID NO:41 is identical to instant SEQ ID NO:2, and is therefore an isolated soluble cytokine receptor polypeptide comprising a sequence of amino acids as shown in SEQ ID NO:2 from amino acid 22-231.

While the recitation regarding formation of a multimeric receptor complex with various components is noted, these limitations appear to refer to inherent properties of a polypeptide comprising amino acid residues 22-231 of SEQ ID NO:2.

Applicant's arguments regarding the priority date of the instant claims are acknowledged, and have been addressed supra.

The Examiner maintains that the reference is available as prior art in view of the effective filing date of the instant claims and that the teachings anticipate the instant claimed invention.

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**Conclusion**

14. Claims 1, 47, 51-53, 68, 70, 72-80 and 83-86 appear to be allowable.

15. Applicant's amendment necessitated the new grounds of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jessica Roark, whose telephone number is (571) 272-0848. The examiner can normally be reached Monday from 8:30 to 5:00, and Tuesday/Thursday from 10:00 to 4:00. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached at (571) 272-0841. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number for before Final submissions is (703) 872-9306.

Jessica Roark, Ph.D.  
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January 26, 2004

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